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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. FSIS-2017-0026]

RIN 0583-AD58

Eligibility of Honduras to Export Poultry Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal poultry products inspection regulations to add Honduras to the list of countries eligible to export poultry products to the United States. The FSIS review of Honduras' laws, regulations, and inspection system demonstrated that its poultry slaughter inspection system is equivalent to the system FSIS has established under the Poultry Products Inspection Act (PPIA) and its implementing regulations.

DATES: Effective [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 720-0089.

SUPPLEMENTARY INFORMATION: Under this final rule, Honduras will be permitted to export to the United States only raw poultry products, such as whole carcasses produced in certified Honduran establishments, because FSIS only assessed Honduras' poultry slaughter inspection system. Honduras would need to request an equivalence determination and submit additional information records for FSIS to review before FSIS would allow Honduras to export heat-treated poultry products, such as cooked or canned product, to the United States. All products that Honduras exports to the United States will be subject to re-inspection at ports of entry by FSIS inspectors. At this time, Honduras is unable to ship raw poultry product to the United States because it is not recognized by APHIS as being free of Newcastle Disease (ND).

Background

On April 13, 2016, FSIS published a proposed rule in the **Federal Register** (81 FR 21758) to add Honduras to the list of countries eligible to export poultry products to the United States (9 CFR 381.196(b)). This final rule is consistent with the proposed rule.

As explained in the proposed rule, section 17 of the PPIA (21 U.S.C. 466) prohibits importation into the United States of slaughtered poultry, or parts or products thereof, of any kind unless they are healthful, wholesome, fit for human food, not

adulterated, and contain no dye, chemical, preservative, or ingredient that renders them unhealthful, unwholesome, adulterated, or unfit for human food. Under the PPIA and the regulations that implement it, poultry products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States. Under the regulations at 9 CFR 381.196, FSIS sets out the procedures by which foreign countries may become eligible to export poultry and poultry products to the United States.

Section 381.196(a) requires a foreign country's poultry inspection system to include standards equivalent to those of the United States and to provide legal authority for the inspection system and its implementing regulations that is equivalent to that of the United States. Specifically, a country's legal authority and regulations must impose requirements equivalent to those of the United States with respect to: (1) Ante-mortem and post-mortem inspection by, or under the direct supervision of, a veterinarian, or other employees or licensees of the system under the direct supervision of veterinarians; (2) official controls by the national government over establishment construction, facilities, and equipment; (3) direct and continuous official supervision of slaughtering of poultry and processing of poultry products by

inspectors to ensure that product is not adulterated or misbranded; (4) complete separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of product at establishments certified to export; (7) official controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the PPIA and its implementing regulations (9 CFR 381.196(a)(2)(ii)).

The country's inspection system must also impose requirements equivalent to those of the United States with respect to: (1) Organizational structure and staffing, so as to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) ultimate control and supervision by the national government over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification, and residue standards; and (7) any other inspection requirements (9 CFR 381.196(a)(2)(i)).

Evaluation of the Honduran Poultry Inspection System

In 2003, the government of Honduras requested approval to export poultry products to the United States. Honduras stated

that if approved, its immediate intent was to export raw poultry carcasses to the United States. FSIS then began to evaluate the Honduras poultry slaughter inspection system to determine whether it is equivalent to that of the United States.

FSIS conducted a document review to evaluate the laws, regulations, and other documentation used by Honduras to execute its poultry inspection system. FSIS examined the information submitted by Honduras to verify that the following equivalence components were addressed satisfactorily with respect to standards, activities, resources, and enforcement: (1)

Government Oversight; (2) Statutory Authority and Food Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Point Systems; (5) Chemical Residue Testing Programs; and (6) Microbiological Testing Programs. The document review was satisfactory to FSIS, and FSIS scheduled an on-site review to evaluate all aspects of the Honduran poultry inspection program.

In November 2005, FSIS conducted an on-site audit of the Honduran poultry inspection program and identified systemic deficiencies within three equivalence components: Government Oversight, Sanitation, and HACCP. In response to this audit, Honduras submitted a corrective action plan that addressed FSIS's findings.

In June 2009, FSIS conducted a second on-site audit to verify whether all outstanding issues identified during the previous audit had been resolved. Through the 2009 audit, FSIS verified that Honduras implemented corrective actions in response to the previous audit findings, and these corrective actions were working as intended. However, during the 2009 audit, FSIS identified systemic deficiencies not identified in the previous audit. The deficiencies related to the equivalence components of Sanitation, HACCP, and Microbiological Testing Programs.

Following the 2009 on-site audit, Honduras again provided a comprehensive corrective action plan that addressed the findings identified. Corrective actions included implementing new regulations, procedures, measures, and verification activities to ensure uniformity in conducting official inspection activities.

In September 2014, FSIS conducted a third on-site audit to verify that Honduras had satisfactorily addressed all the findings of the November 2005 and June 2009 audits and had met the FSIS criteria for all six equivalence components. The evaluation of all documentation provided by Honduras since the 2009 audit (corrective actions taken in response to the 2009 audit findings, regulatory updates, new performance standards, and new microbiological laboratory procedures and analyses)

supported the decision to perform the third audit. The auditor verified that all corrective actions in response to the 2009 audit findings were implemented as described and working as intended. There were no new audit findings from the 2014 on-site audit. The auditor concluded that the Honduran poultry regulatory system cumulatively achieves a level of protection equivalent to that provided by the United States poultry inspection system.

Consequently, on April 13, 2016, FSIS published a proposed rule to add Honduras to the list of countries eligible to export raw poultry products, such as whole carcasses, to the United States, based on its finding that the Honduran poultry slaughter inspection system is equivalent to the United States poultry inspection system. For more detailed information on the FSIS evaluation of the Honduran poultry inspection system, see the proposed rule (81 FR 21758), and for the full audit reports, go to

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports/foreign-audit-reports.

Final Rule

After considering the comments received on the proposed rule, discussed below, FSIS has concluded that the Honduran poultry inspection system is equivalent to the United States

inspection system for raw poultry products. Therefore, FSIS is amending its poultry products inspection regulations to add Honduras to the list of countries eligible to export poultry products to the United States (in 9 CFR 381.196 (b)). Under the FSIS import regulations, the government of Honduras must certify to FSIS that establishments requesting to export poultry products to the United States are operating under requirements equivalent to those of the United States (9 CFR 381.196(a)).

Although a foreign country may be listed in FSIS regulations as eligible to export poultry to the United States, the exporting country's products must also comply with all other applicable requirements of the United States. These requirements include restrictions under 9 CFR part 94 of the Animal and Plant Health Inspection Service (APHIS) regulations, which also regulate the importation of poultry products from foreign countries into the United States. At this time, Honduras cannot ship poultry products to the United States because APHIS does not recognize Honduras as a region free from ND.

Under this final rule, all slaughtered poultry, or parts and products thereof, exported to the United States from Honduras will be subject to re-inspection at the United States ports of entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count.

FSIS will conduct other types of re-inspection activities, such as taking product samples for laboratory analysis to detect any drug or chemical residues that may render the product unsafe, as well as any species or product composition violations that would render the product economically adulterated. Products that pass re-inspection will be stamped with the official mark of inspection and allowed to enter United States commerce. If they do not meet U.S. requirements, they will be refused entry and within 45 days will have to be returned to the country of origin, destroyed, or converted to animal food (subject to approval by FDA), depending on the violation. The import re-inspection activities can be found on the FSIS Web site at https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures.

In addition, should Honduras meet APHIS requirements,

Honduran poultry products will be eligible for importation into
the United States only if they are from animals slaughtered on
or after the effective date of this final rule.

Summary of Comments and Responses

FSIS received nine comments on the proposed rule. Seven of the comments were from individuals; one comment was from a consumer advocacy group; and another comment was from a not-for-profit corporation that promotes poultry industry trade associations in Central America. Of the nine comments, five

were against the proposed rule, including the consumer advocacy group. Three individuals and the one trade advocate were in support of the proposed rule.

The following is a discussion of the relevant issues raised in the comments.

Comments: Several commenters objected to the rule for economic reasons. Commenters stated that poultry imports could undermine U.S. poultry production leading to decreased demand for domestic supply and unemployment for U.S. poultry producers. The commenters were concerned that the increased competition in the poultry market will negatively impact domestic producers by putting downward pressure on the market price and potentially edging domestic producers out of the market.

An individual commenter questioned whether there is a need for imported poultry and whether the rule is necessary because of a lack of domestic supply. Another commenter expressed concern about using U.S. tax dollars to help Honduras reach equivalency in its inspection systems, so the country could be approved by FSIS for exports.

Response: Economic and market realities make it unlikely that the increased amounts of poultry imports from Honduras will lead to unemployment for domestic producers. Should Honduras meet APHIS requirements, FSIS estimates Honduran exports will comprise 0.05 percent of the U.S. market annually the first

three years. FSIS does not believe that this rule will adversely affect the U.S. poultry industry because the volume of trade that results from this rule will likely be small and have little effect on supply and prices. Demand for domestically produced poultry will not be affected because FSIS expects the market price to remain stable.

FSIS has conducted a comprehensive cost-benefit analysis of the rule and determined it to be advantageous to both countries. The preliminary and final analyses recognize that any significant effects of the rule will come through efficiency gains.

Additionally, FSIS has an appropriated annual budget to review documents and audit countries' inspection systems to assess whether they are equivalent to the FSIS inspection system. Other than explaining FSIS requirements, FSIS does not aid countries in becoming equivalent. These activities will not lead to direct competition because there is no expected market price increase resulting from the rule.

Comment: One commenter expressed concern about ND in Honduras. This commenter stated that FSIS should test individual poultry products.

Response: Although Honduras may be listed in FSIS's regulations as eligible to export poultry products to the United States, the products must also comply with all other

applicable requirements of the United States, including those of APHIS, before any products can enter the United States.

APHIS is responsible for preventing the entry of foreign animal diseases into the livestock population of the United States. APHIS determines the animal health status of foreign countries or regions for certain diseases, and this process is outlined in Title 9 CFR Part 92. These animal health status determinations help establish the import requirements for livestock and products derived from them.

As is discussed above, at this time, APHIS does not allow Honduras to export raw poultry to the U.S. because Honduras is not recognized by APHIS as a region free of ND. Honduras has requested that APHIS recognize it as free of ND, and APHIS is conducting a review and evaluation. If APHIS determines that Honduras is free of ND, it will make its evaluation available for public comment through a document published in the Federal Register.

FSIS and APHIS work closely together to ensure that all poultry products imported into the United States comply with the regulatory requirements of both agencies. In 1985, FSIS and APHIS signed a memorandum of understanding (MOU) in which both agencies agreed to cooperate in meeting their respective needs for information on disease surveillance, diagnostic testing, investigations, trace backs, and animal and public health

emergencies. Information exchange between the two agencies is necessary to reduce the spread of animal disease, while providing a wholesome food supply.

The MOU is updated periodically to ensure that it addresses matters of importance to both agencies. The MOU was last updated November 20, 2014. In accord with this MOU, FSIS and APHIS established procedures for communication between the two agencies regarding the inspection, handling, and disposition of imported poultry products. APHIS and FSIS communicate regularly to ensure that products APHIS has restricted from entering the United States because of animal disease concerns are not imported into the United States.

Comment: One commenter expressed concerns about the length of time it took Honduras to achieve equivalence and how Honduras plans to maintain equivalence in the future. The commenter stated that the FSIS 2014 audit report does not contain information about the number of inspectors assigned to poultry slaughter lines, the workload ratio of the assigned inspectors, or the line speeds in Honduras. The commenter also stated concerns about the reliability of establishments' — interventions and the CCA's sampling protocols.

Response: Honduras meets current standards with regard to line speeds and the workload ratio of assigned inspectors.

During the 2014 audit, FSIS observed online inspection of 140

birds per minute with 4 online inspectors, or 35 birds per minute per inspector. The Honduran food safety system, food safety interventions and sampling protocols were assessed during the FSIS on-site audits.

FSIS assesses a country's food regulatory system in terms of six equivalence components and uses its findings from the assessment in deciding whether to grant eligibility to the country for the importation of its poultry products into the United States. Based on the 2014 follow-up on-site audit, FSIS determined that Honduras fully met the criteria within those six equivalence components, in accordance with 9 CFR 327.2. FSIS tentatively concluded that, as implemented, the Honduran poultry slaughter inspection system is equivalent to the United States poultry inspection system. The details of Honduran compliance with those components can all be found on the FSIS Web site at: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports.

FSIS ensures that countries maintain equivalence through a three-part process, involving: (1) recurring equivalence reviews (e.g., through use of the country Self Reporting Tool or other documentation from the Central Competent Authority) of the exporting country's applicable laws and regulations; (2) periodic on-site equivalence verification audits in the

exporting country; and (3) ongoing point-of-entry (POE) reinspection of shipments received from the exporting country. These POE activities include examination of products for defects, condition-of container examinations, and laboratory analysis of product samples.

For all these reasons, therefore, concerns about the length of time it took Honduras to achieve equivalence and how Honduras plans to maintain equivalence in the future are unwarranted. Honduras has sampled and tested for Salmonella in raw poultry since the 2005 and 2009 audits, and has started sampling and testing for Campylobacter in raw poultry since - the 2014 audit. Honduras has implemented requirements that are equivalent to FSIS's Poultry Slaughter Rule (79 FR 49565) to ensure pathogen reduction during the slaughter of poultry. The deficiencies have been remedied, and the Honduran inspection system will be subject to ongoing verification to ensure that it continues to maintain standards equivalent to those of the United States.

Comments: The commenters who supported the proposed rule generally cited the economic benefits of increased trade.

Response: FSIS agrees the rule is mutually beneficial to both the U.S. and Honduran economies.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated a "non-significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Expected Costs of the Final Rule

This final rule adds Honduras to the list of countries eligible to export raw poultry to the United States. However, because of animal disease restrictions, APHIS regulations currently prohibit Honduras from immediately shipping raw poultry products to the United States. Honduran establishments are currently eligible to export raw and processed beef and veal, raw and processed lamb and mutton, raw and processed goat as well as processed pork. According to data from the government of Honduras, Honduras intends to certify one establishment as

eligible to export raw poultry to the United States.¹ Should the country meet APHIS requirements, the expected export volume for this establishment for the first three years is 10,211 Metric Tons (MT). This is expected to increase to 11,231 MT in year four and 12,355 MT in year five.²

The U.S. poultry industry is one of the most competitive agricultural industries in the world. U.S. establishments slaughtered 18.6 million MT of young chickens in 2017.³

Approximately 3.0 million MT of young chickens slaughtered in the United States were exported in 2017 and 0.056 million MT were imported⁴.

The importation of poultry products from Honduras is expected to have a minimal impact on the United States poultry market. Should Honduras meet APHIS requirements, FSIS estimates Honduran exports would comprise 0.05 percent (10,211 MT from Honduras compared to a Unites States slaughter volume of 18.6 million MT in 2017) of the United States market annually the first three years. FSIS estimates Honduran exports would continue to comprise 0.06 percent of the U.S. market the fourth

¹ Honduras currently has only two establishments certified for meat exports to the United States. Therefore, it is unlikely we will see a significant increase in the number of establishments eligible to export poultry from Honduras.

² Source: Correspondence with the Government of Honduras.

https://apps.fas.usda.gov/psdonline/circulars/livestock poultry.pdf

⁴ USDA Foreign Agricultural Service. Market and Trade Data/PSD online/Reports and Data: Exports Market year 2017.

https://apps.fas.usda.gov/psdonline/app/index.html#/app/downloads http://apps.fas.usda.gov/psdonline/circulars/livestock poultry.pdf

year and increase to 0.07 percent the fifth year. FSIS projects that Honduras would not alter the U.S. poultry supply and would not have an impact on domestic poultry prices. Therefore, FSIS projects that establishments in the United States would not see the negative effects that could come from a decrease in price as a result of increased competition.

Companies based in Honduras that export to the United States or United States companies that export products from Honduras to the United States would incur standard costs such as export fees and freight and insurance costs. However, those companies would be willing to bear these costs because of the expected benefits associated with selling their products to the U.S.

Expected Benefits of the Final Rule

Should Honduras meet APHIS requirements, FSIS expects to see an increase in trade between Honduras and the United States. The volume of poultry exported from Honduras is likely to be small and is expected to have little to no effect on domestic poultry supplies or prices. Therefore, consumers will not benefit from a decrease in price that would result from increased competition. However, Latin American preferences for dark meat compliment American preferences for white meat.

Therefore, Honduran establishments will benefit if they export surplus white meat to the United States. While the export of

white meat from Honduras may be minimal compared to overall consumption in the United States, these exports may be significant enough in the long run to influence domestic prices in Honduras.⁵

In addition, the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR), implemented in 2006, sought to level the playing field and increase trade between the United States and the six CAFTA-DR trading partners, including Honduras. FSIS expects this final rule will increase trade, benefiting firms and consumers in the United States and Honduras, especially within the agricultural sector. Providing market access to Honduran establishments ensures similar access will be given to United States firms. American firms have already benefited from CAFTA-DR, with agricultural exports (including wheat, live animals and red meat) to Honduras nearly doubling (82.5 percent) between 2006 and 2017 and is expected to rise even further in the future.

Regulatory Flexibility Act Assessment

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⁵ Haley, Mildred M. (May 2001). Changing Consumer Demand for Meat: The U.S. Example, 1970-2000. In A. Regmi, *Changing Structure of Global Food Consumption and Trade* (pp.41-48). (Economic Research Service Outlook No. WRS-01-1) Washington, DC.

 $^{^6}$ United States Department of Agriculture. FACT SHEET on Dominican Republic-Central America-United States Free Trade Agreement (Release No. 0237.08). Retrieved on March 18, 2015 from

http://www.usda.gov/wps/portal/usda/usdamediafb?contentid=2008/09/0237.xml&printable=true&contentidonly=true.

Ource: FAS Global Agricultural Trade System - FAS Agricultural Total Exports to Honduras

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), this final rule will not have a significant impact on a substantial number of small entities in the United States. As mentioned above, the expected trade volume is very small. Therefore, the action should not have a significant impact on small entities that produce poultry products domestically.

Paperwork Reduction Act

No new paperwork requirements are associated with this final rule. Foreign countries wanting to export poultry and poultry products to the United States are required to provide information to FSIS certifying that their inspection system provides standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication and officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this proposal on-line through the FSIS Web page located at: http://www.fsis.usda.gov/federal-register.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Constituent Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: http://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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List of Subjects in 9 CFR Part 381

Imported products.

For the reasons set out in the preamble, FSIS is amending 9 CFR part 381 as follows:

PART 381--POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR 2.7, 2.18, 2.53.

§ 381.196 [Amended]

2. Section 381.196 is amended in paragraph (b) by adding "Honduras" in alphabetical order to the list of countries.

Done in Washington, DC.

Carmen M. Rottenberg Administrator.

[FR Doc. 2019-06662 Filed: 4/4/2019 8:45 am; Publication Date: 4/5/2019]